

REMARKS

Applicants would first like to thank the Examiner for the courtesy extended to attorney for Applicants, Shannon McGarrah, during a May 14, 2009 interview.

Claims 1-9, as amended, are pending in this application. Claim 8 is withdrawn without prejudice. Applicants reserve the right to file one or more continuation, divisional, or continuation-in-part applications directed to any withdrawn subject matter. No new matter is added. Applicants respectfully request entry of the amendments.

I. The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 1-7 and 9-11 are rejected as allegedly obvious under 35 U.S.C. § 103(a) over Reinhart, EP 0 687 257 A1 (Reinhart) in view of Reisbick *et al.*, Handbook of Essential Fatty Acid Biology: Biochemistry, Physiology, and Behavioral Neurobiology: Chapter 17 pp. 397-426 (“Riesbick”). Applicants respectfully traverse this rejection for at least the following reasons.

Applicants submit that one of ordinary skill in art after reading Reinhart would not have reasonably expected that the pet food product of Reinhart would have a positive effect on animal behavior, as Applicants have used that term in the claims. As the Examiner is aware, there must have been at the time of the invention a reasonable expectation of success. *Amgen, Inc. v. Chingai Pharmaceutical Co.*, 927 F.2d 1200, 1207-1208 (Fed. Cir. 1991), cert. denied 502 U.S. 856 (1991).

The pending claims encompass methods for influencing behavior in an animal, the methods comprising systemically administering to the animal in need thereof a diet comprising at least about 1% by weight of an omega-3 fatty acid or mixture of omega-3 fatty acids as measured on a dry matter basis.

The office action states “[i]t would have been obvious to one of ordinary skill in the art that animals treated with the pet food product of Reinhart would influence the behavior of the animals because Reinhart teaches that pet food product improved the general comfort and well-being of the animals.” (See office action at page 4). However, the office action mischaracterizes Reinhart. Reinhart actually discloses:

It will be appreciated that feeding pet animals with a diet consisting essentially of the pet food products as hereinbefore described not only reduces allergic and inflammatory conditions in the skin of the animals thereby improving the general comfort and well-being of the animals, but there is also a cosmetic effect in that the appearance of the skin of the animals is improved. In particular, by preventing and/or alleviating symptoms of skin diseases such as dermatitis and pruritis unsightly skin conditions can be avoided or diminished giving the animals an attractive, healthy appearance.

(See Reinhart at paragraph [0009]).

Thus, the phrase "improving the general comfort and well-being" disclosed in Reinhart is relative to an animal that is experiencing an allergic or inflammatory condition.

In contrast, the term "behavior" as recited by the claims includes:

[b]ehavior which can be altered for the positive by the systemic administration of omega-3 fatty acids include memory; learning; disorientation including at least one of awareness of surroundings, circling, aimless activity, inappropriate vocalization; interactions including at least one of family recognition, animal recognition, family interaction, animal interaction, greeting enthusiasm, attention seeking, response to verbal commands; activity such as agility and level of activity; irregular sleep pattern; housetraining; and any behavior associated with ARCD.

(See specification at paragraph [0009]).

Clearly, Reinhart could not teach or suggest methods of influencing behavior as recited by the instant claims based merely on Reinhart's teaching of reducing allergic and inflammatory conditions. Indeed, there must have been at the time of the invention a motivation to modify the teachings of the references cited. *Ecolochem, Inc. v. Southern California Edison Company*, 227 F.3d 1361, 1372 (Fed. Cir. 2000). Applicants respectfully submit that nothing in Reinhart teaches or suggests to one of ordinary skill in the art methods for influencing behavior in an animal as recited by the pending claims.

Applicants further submit that the claims have been amended to recite the language “in need thereof.” The subject matter recited in the pending claims is not obvious, based upon the Reinhart reference alone or in combination with the Riesbick reference, because the Office has failed to show that there was an intent to use the compositions comprising at least about 1% by weight of an omega-3 fatty acid or mixture of omega-3 fatty acids as measured on a dry matter basis for influencing behavior in an animal. When a claim recites a method of treating a disorder to be performed on a patient ‘in need of’ such treatment, the proper construction of the claim is that the method be practiced in order to treat that specific disorder. *Jansen v. Rexall Sundown*, 342 F.3d 1329, 1333-34, 68 U.S.P.Q.2d 1154, 1157-58 (Fed. Cir. 2003); *Rapoport v. Dement*, 254 F.3d 1053, 1060-61 (Fed. Cir. 2001). In *Rapoport v. Dement*, the claim under dispute recited:

A method of treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . .

254 F.3d at 1060. The court reasoned that the phrase “to a patient in need of such treatment” in the body of the claim would not have a proper antecedent basis without treating the claim preamble as claim feature. *Id.* at 1059. The court further explained that this claim feature required that the azapirone compound be administered in order to treat sleep apneas. *Id.* at 1060-61 (analyzing whether an allegedly anticipatory reference disclosed administration of an azapirone compound with intent to cure sleep apneas and stating that the reasons for administering the compound were relevant to an anticipation analysis). A subsequent Federal Circuit decision confirmed the conclusion of the *Rapoport* court. *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58 (confirming that the *Rapoport* method of treatment claim required that the method be practiced in order to treat sleep apneas). Thus, although the present rejection is an obviousness rejection and not an anticipation rejection, the claim must still be construed accordingly.

In *Jansen*, a similar method of treatment claim was interpreted to require that a drug combination be administered in order to treat the specified disorder. *Id.* In *Jansen*, the claim under dispute recited:

1. A method of treating or preventing macrocytic-megaloblastic anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B12 deficiency which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof comprising at least about 0.5 mg. of vitamin B12 and at least about 0.5 mg. of folic acid.

Id. at 1330, 68 U.S.P.Q.2d at 1155. Relying in part on the *Rapoport* decision, the court interpreted the claim preamble as a statement of the “intentional purpose for which the method must be performed,” rather than “a statement of effect that may or may not be desired or appreciated,” thus rendering the preamble as an element of the claim. *Id.* at 1333, 68 U.S.P.Q.2d at 1158. That the specific type of anemia and the “in need” language was added to the claim during prosecution to achieve allowance of the claim bolstered the court’s conclusion that the two phrases should be read together and considered an element of the claim. *Id.* at 1334, 68 U.S.P.Q.2d at 1158. As stated by the court:

. . . that “need” must be recognized and appreciated, for otherwise the added phrases do not carry the meaning that the circumstances or their addition suggest they carry. In other words, administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megoblastic anemia is not practicing the claimed method, because Jansen limited his claims to treatment or prevention of that particular condition in those who need such treatment or prevention. (emphasis added).

Id. at 1334, 68 U.S.P.Q.2d at 1158. Accordingly, a method claim further reciting “in need thereof” language should be properly construed such that the method is practiced with intent to reduce the particular disorder or symptom recited in the claim.

Here, as in *Jansen* and *Rapoport*, the pending claims recite that the methods are used on animals “in need thereof.” The Office’s analysis of the claims has failed to take into account this phrase. Indeed, the Office has not identified any portion of the cited

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Here, as in *Jansen* and *Rapoport*, the pending claims recite that the methods are used on animals “in need thereof.” The Office’s analysis of the claims has failed to take into account this phrase. Indeed, the Office has not identified any portion of the cited

references that discloses or suggests the intent to practice the claimed methods for the purpose recited in the claims. There is nothing in either reference that discloses an intent to influence behavior in an animal. Indeed, the only disorder or symptom mentioned in the Reinhart is reducing inflammatory and allergic skin response and Riesbick only discloses learning and performance. As the M.P.E.P. states, “[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.” (M.P.E.P. § 2141). “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* The Office has failed to put forward a sufficient articulated reason as to why Applicants' claims are obvious in view of the cited references,

For at least the foregoing reasons, Applicants respectfully submit that the rejection of claims 1-7 and 9-11 as obvious under 35 U.S.C. § 103 is improper and should be withdrawn.

II. Double Patenting Rejections

Claims 1-5, 7, and 9-11 are provisionally rejected under the judicially created doctrine of “obviousness-type double patenting” in view of claims 1-20 of U.S. patent application no. 10/912,864.

Claims 1-5, 7, and 9-11 are provisionally rejected under the judicially created doctrine of “obviousness type double patenting” in view of claims 1, 7, 13, 19, and 26-29 of U.S. patent application no. 11/057,718.

Without acquiescing to the propriety of these rejections, Applicants respectfully point out that each of the rejections is a provisional obviousness-type double patenting rejection between two applications, since the claims of Application Nos. 10/912,864 and 11/057,718 have not in fact been patented. MPEP 804 (I)(B) (page 800-19) states,

If the “provisional” double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the

"provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

Accordingly, if these are the only rejections remaining in this case, Applicants respectfully request withdrawal of each of the rejections in accordance with MPEP 804 (l)(B).

IV. Conclusion

For at least the reasons discussed above, Applicants believe that claims 15 – 30 are allowable. Further and favorable consideration is solicited. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

Respectfully submitted,
Yu et al.

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Shannon E. McGarrah

By: Shannon E. McGarrah
Reg. No.: 55,442
COLGATE-PALMOLIVE COMPANY
909 River Road; P.O. Box 1343
Piscataway, NJ 08855-1343
Telephone (732) 878-7151